SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2016

_____

BioLineRx Ltd.

(Translation of Registrant's name into English)

_____

2 HaMa'ayan Street
Modi'in 7177871, Israel
(Address of Principal Executive Offices)

_____

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

Yes ☐ No ☒

On May 17, 2016, the Registrant will issue a press release announcing its financial results for the three months ended March 31, 2016. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of March 31, 2016, and for the three months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated May 17, 2016;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of March 31, 2016, and for the three months then ended;

Exhibit 3 - Registrant's operating and financial review as of March 31, 2016, and for the three months then ended.

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioLineRx Ltd.

By: /s/ Philip Serlin
Philip Serlin
Chief Financial and Operating Officer

Dated: May 17, 2016

Exhibit 1

For immediate release

BioLineRx Reports First Quarter 2016 Financial Results

Tel Aviv, Israel, May 17, 2016 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reports its financial results for the first quarter ended March 31, 2016.

Highlights and achievements during the first quarter of 2016, and to date:

- Signing of immuno-oncology collaboration with Merck for BL-8040 Phase 2a study in pancreatic cancer
- Successful top-line results from Phase 2a study for BL-8040 in r/r AML
- Continued ramp-up of Phase 2b study for BL-8040 as consolidation treatment for AML patients following standard induction treatment
- Initiation of Phase 2 study for BL-8040 in allogeneic stem-cell transplantation
- Receipt of medical device classification for BL-7010 for celiac disease in Europe
- BL-5010 for non-surgical removal of skin lesions receives CE mark and begins initial product launch in Europe

Expected upcoming significant milestones for the remainder of 2016:

- Initiation of Phase 2a study for BL-8040 in combination with KEYTRUDA®, in patients with metastatic pancreatic cancer, expected mid-year
- Full set of data from Phase 2a study for BL-8040 in r/r AML to be provided at an upcoming US-based scientific conference
- Partial results from Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by end of 2016
- Initiation of efficacy study in gluten sensitivity for BL-7010
- Roll-out of BL-5010 product launch by Omega to additional countries and selection of 2nd OTC indication for development

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "During the first quarter of 2016, we made significant progress in advancing BL-8040, our lead oncology platform. We announced successful results in our Phase 2a study for relapsed and refractory AML and we continue to push forward in our Phase 2b trial in an earlier treatment line for AML - as a consolidation treatment following standard induction treatment. We also announced our entering into the exciting field of immuno-oncology, through our collaboration with Merck on a Phase 2a study to investigate BL-8040 in combination with KEYTRUDA® for the treatment of pancreatic cancer. In addition, we are progressing with our strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. Novartis has flagged several pre-clinical projects, which we intend to bring into our pipeline over the next few months. With $45 million of cash on our balance sheet as of the end of the first quarter, we are well positioned to carry out our strategic and operational plans through the end of 2018, and look forward to achieving our expected milestones during the second half of 2016."

Financial Results for First Quarter Ended March 31, 2016

Research and development expenses for the three months ended March 31, 2016 were $2.5 million, a decrease of $0.7 million, or 20.9%, compared to $3.2 million for the three months ended March 31, 2015. The decrease resulted primarily from the conclusion of one of the clinical trials for BL-8040 in 2015, and the wind-down of a second clinical trial for BL-8040 during the 2016 period.

Sales and marketing expenses for the three months ended March 31, 2016 were $0.2 million, substantially similar to the comparable period in 2015.

General and administrative expenses for the three months ended March 31, 2016 were $1.0 million, an increase of $0.1 million, or 15.5%, compared to $0.9 million for the three months ended March 31, 2015. The small increase was the cumulative effect of an increase in several categories of expenses, none of which individually was material.

The Company's operating loss for the three months ended March 31, 2016 amounted to $3.8 million, compared with an operating loss of $4.3 million for the corresponding 2015 period.

Non-operating income (expenses) for the three months ended March 31, 2016 and 2015 were not material, and primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Financial income (expenses), net for the three months ended March 31, 2016 and 2015 were not material, and primarily relate to investment income earned on bank deposits, as well as banking fees.

The Company's net loss for the three months ended March 31, 2016 amounted to $3.5 million, compared with a net loss of $4.3 million for the corresponding 2015 period.

The Company held $45.0 million in cash, cash equivalents and short-term bank deposits as of March 31, 2016

Net cash used in operating activities was $4.2 million for the three months ended March 31, 2016, compared with net cash used in operating activities of $3.5 million for the 2015 period. The $0.7 million increase in net cash used in operating activities was primarily the result of a decrease in trade payables and accruals.

Net cash provided by investing activities for the three months ended March 31, 2016 was $1.7 million, compared to net cash used in investing activities of $20.7 million for the corresponding 2015 period. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the three months ended March 31, 2016 was $1.6 million, compared to net cash provided by financing activities of $26.5 million for the corresponding 2015 period. The decrease in cash flows from financing activities reflects the underwritten public offering completed by the Company in March 2015.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its first-quarter end March 31, 2016 results today, May 17, 2016, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-407-2553 from the US, or +972-3-918-0644 internationally. The call will also be available via live webcast through BioLineRx's website. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-295-2634 from the US or +972-3-925-5945 internationally. The replay will be available through May 20, 2016.

(Tables follow)

About BioLineRx
BioLineRx is a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds, primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment, and has recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on Facebook, Twitter, and LinkedIn.

Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 10, 2016. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2015	March 31, 2016
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,544	4,584
Short-term bank deposits	42,119	40,423
Prepaid expenses	229	466
Other receivables	291	396
Total current assets	48,183	45,869
NON-CURRENT ASSETS		
Long-term prepaid expenses	58	56
Property and equipment, net	2,909	2,859
Intangible assets, net	152	157
Total non-current assets	3,119	3,072
Total assets	51,302	48,941
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	1,910	1,465
Other	1,137	1,001
Total current liabilities	3,140	2,559
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	344	320
Warrants	208	60
Total non-current liabilities	552	380
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,692	2,939
EQUITY		
Ordinary shares	1,455	1,459
Share premium	196,201	197,792
Other comprehensive income (loss)	(1,416)	(1,416)
Capital reserve	10,735	11,021
Accumulated deficit	(159,365)	(162,854)
Total equity	47,610	46,002
Total liabilities and equity	51,302	48,941

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended March 31,	
	2015	2016
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(3,211)	(2,539)
SALES AND MARKETING EXPENSES	(260)	(248)
GENERAL AND ADMINISTRATIVE EXPENSES	(856)	(989)
OPERATING LOSS	(4,327)	(3,776)
NON-OPERATING INCOME (EXPENSES), NET	(40)	148
FINANCIAL INCOME	73	143
FINANCIAL EXPENSES	(17)	(4)
NET LOSS AND COMPREHENSIVE LOSS	(4,311)	(3,489)
	in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.101)	(0.064)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	42,506,905	54,870,561

BioLineRx Ltd.
CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	Ordinary shares	Share premium	Other comprehensive income (loss)	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2015	1,055	167,331	(1,416)	9,800	(144,965)	31,805
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2015:						
Issuance of share capital, net	365	26,095	-	-	-	26,460
Share-based compensation	-	-		234	-	234
Comprehensive loss for the period	-	-	-	-	(4,311)	(4,311)
BALANCE AT MARCH 31, 2015	1,420	193,426	(1,416)	10,034	(149,276)	54,188

	Ordinary shares	Share premium	Other comprehensive income (loss)	Capital reserve	Accumulated Deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2016	1,455	196,201	(1,416)	10,735	(159,365)	47,610
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2016:						
Issuance of share capital , net	4	1,591	-	-	-	1,595
Share-based compensation	-	-	-	286	-	286
Comprehensive loss for the period	-	-	-	-	(3,489)	(3,489)
BALANCE AT MARCH 31, 2016	1,459	197,792	(1,416)	11,021	(162,854)	46,002

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Three months ended March 31,	
	2015	2016
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(4,311)	(3,489)
Adjustments required to reflect net cash used in operating activities (see appendix below)	843	(695)
Net cash used in operating activities	(3,468)	(4,184)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(31,153)	(10,300)
Maturities of short-term deposits	10,634	12,102
Purchase of property and equipment	(149)	(137)
Purchase of intangible assets	(2)	(11)
Net cash provided by (used in) investing activities	(20,670)	1,654
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	26,460	1,595
Repayments of bank loan	-	(23)
Net cash provided by financing activities	26,460	1,572
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,322	(958)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,790	5,544
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(37)	(2)
CASH AND CASH EQUIVALENTS - END OF PERIOD	8,075	4,584

BioLineRx Ltd.
APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Three months ended March 31,	
	2015	2016
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	102	122
Long-term prepaid expenses	(1)	2
Interest on short-term deposits	(9)	(106)
Share-based compensation	234	286
Exchange differences on cash and cash equivalents	37	2
Interest and linkage differences on bank loan	-	(1)
Loss (gain) on adjustment of warrants to fair value	40	(148)
	403	157
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(459)	(342)
Increase (decrease) in accounts payable and accruals	899	(510)
	440	(852)
	843	(695)
Supplementary information on investing activities not involving cash flows:		
Property and equipment acquired on supplier trade credit	482	-
Supplementary information on interest received in cash	30	103

Exhibit 2

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF MARCH 31, 2016

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF MARCH 31, 2016

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Accumulated deficit	(159,365)	(162,854)
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The accompanying notes are an integral part of these condensed financial statements.

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(UNAUDITED)

	Three months ended March 31,	
	2015	2016
	in USD thousands	
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(UNAUDITED)

	Three months ended March 31,	
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BioLineRx Ltd.
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The accompanying notes are an integral part of these condensed financial statements.

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003. Since incorporation, BioLineRx and its consolidated entities (collectively, the "Company") have been engaged in the development of therapeutics, from pre-clinical development to advanced clinical trials, for a wide range of medical needs.

In February 2007, BioLineRx listed its ordinary shares on the Tel Aviv Stock Exchange ("TASE") and they have been traded on the TASE since that time. Since July 2011, BioLineRx's American Depositary Shares ("ADSs") have also been traded on the NASDAQ Capital Market.

The Company has been engaged in drug development since its incorporation. Although the Company has generated significant revenues from a number of out-licensing transactions, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

b. Approval of financial statements

The condensed consolidated interim financial statements of the Company for the three months ended March 31, 2016 were approved by the Board of Directors on May 17, 2016, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.

NOTE 2 – BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of March 31, 2016 and for the three months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a fair statement of financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2015 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of the interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2015 and for the year then ended.

NOTE 4 – ISSUANCES OF SHARE CAPITAL

a. Underwritten public offerings of American Depositary Shares

In March 2015, the Company completed an underwritten public offering of 14,375,000 ADSs at a public offering price of $2.00 per ADS. The offering raised a total of $28.8 million, with net proceeds of approximately $26.5 million, after deducting fees and expenses.

b. Share purchase agreement with Lincoln Park Capital

In May 2014, BioLineRx and Lincoln Park Capital Fund ("LPC"), entered into a $20 million, 36-month purchase agreement, whereby LPC agreed to purchase, from time to time, up to $20 million of BioLineRx's ADSs, subject to certain limitations, during the 36-month term of the purchase agreement.

During the three months ended March 31, 2016, BioLineRx sold a total of 1,550,853 ADSs to LPC for aggregate gross proceeds of $1,627,000. In connection with these issuances, a total of 38,772 ADSs was issued to LPC as a commitment fee and a total of $33,000 was paid to Oberon Securities as a finder's fee. On a cumulative basis, from the effective date of the purchase agreement through the approval date of these financial statements, BioLineRx has sold a total of 2,843,454 ADSs to LPC for aggregate gross proceeds of $4,270,000. In connection with these issuances, a total of 71,087 ADSs was issued to LPC as a commitment fee and a total of $85,000 was paid to Oberon Securities as a finder's fee.

NOTE 5 – SHAREHOLDERS' EQUITY

As of December 31, 2015 and March 31, 2016, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2015	March 31, 2016
Authorized share capital	150,000,000	150,000,000
Issued and paid-up share capital	54,818,057	56,423,601

	In USD and NIS	
	December 31, 2015	March 31, 2016
Authorized share capital (in NIS)	15,000,000	15,000,000
Issued and paid-up share capital (in NIS)	5,481,806	5,642,360
Issued and paid-up share capital (in USD)	1,455,159	1,459,226

Exhibit 3

OPERATING AND FINANCIAL REVIEW

You should read the following discussion of our operating and financial condition and prospects in conjunction with the financial statements and the notes thereto included elsewhere in this 6-K, as well as in our Annual Report on Form 20-F filed on March 10, 2016 (the "Annual Report").

Forward Looking Statements

The following discussion contains "forward-looking statements," including statements regarding expectations, beliefs, intentions or strategies for the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions, and are subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those listed below as well as those discussed in the Annual Report (particularly those in "Item 3. Key Information – Risk Factors"). Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the initiation, timing, progress and results of our preclinical studies, clinical trials and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- competitive companies, technologies and our industry; and
- the impact of the political and security situation in Israel on our business.

Overview

General

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of three main clinical therapeutic candidates: BL-8040, BL-7010 and BL-5010. In addition, we have three other therapeutic candidates in clinical and pre-clinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently. Our focus is principally on the therapeutic areas of oncology and immunology. However, we may also in-license therapeutic compounds outside of these areas in connection with our strategic collaboration with Novartis, as well as to a limited extent for our independent pipeline as the opportunities arise.

Clinical-Stage Pipeline

The following is a description of our three main clinical therapeutic candidates:

- BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for multiple cancer and hematological indications.

  - We commenced a Phase 2a trial for the treatment of relapsed or refractory AML (r/r AML) in June 2013, which was conducted at five world-leading cancer research centers in the U.S. and at five premier sites in Israel. In March 2016, we announced positive top-line results from this study. We plan to present detailed results of the study at an upcoming scientific conference.

  - In addition to the r/r AML study, we are also investigating BL-8040 as a consolidation treatment for AML patients who have responded to standard induction treatment. In this regard, we initiated a significant Phase 2b trial in Germany in August 2015, in collaboration with the German Study Alliance Leukemia Group, as a consolidation treatment for AML patients. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. Up to 194 patients will be enrolled in the trial. The primary endpoint of the study is to compare the relapse-free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. Top-line results of this study are expected in 2018.

  - In March 2015, we reported successful top-line safety and efficacy results from a Phase 1 safety and efficacy trial for the use of BL-8040 as a novel treatment for stem cell mobilization at Hadassah Medical Center in Jerusalem. In March 2016, we announced the initiation of a Phase 2 trial for BL-8040 for allogeneic stem-cell transplantation, to be conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology. Partial results from this study are expected by the end of 2016 and topline results by the end of 2017.

  - In January 2016, we entered into a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. We plan to sponsor and conduct a Phase 2a study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. The study is planned to commence by mid-2016.

- In addition to the above, we are conducting, or planning to conduct, two proof-of-concept studies in other therapeutic indications. In November 2015, we commenced a Phase 1/2 trial, in collaboration with the MD Anderson Cancer Center, for BL-8040 as a treatment for hypoplastic myelodysplastic syndrome (hMDS) and aplastic anemia (AA). This open-label study is designed to evaluate the safety, tolerability and efficacy of the combination of BL-8040 with immunosuppressive therapies (hATG, cyclosporine and methylprednisone). Partial results are expected by the end of 2016. We are also planning to commence a Phase 2a trial for BL-8040 in the second half of 2016, in collaboration with the MD Anderson Cancer Center, for the treatment of AML patients with the FLT3-ITD mutation.

- In September 2013, the FDA granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML; and in January 2014, the FDA granted an Orphan Drug Designation to BL-8040 as a treatment for stem cell mobilization. In January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with G-CSF.

- BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease and gluten sensitivity. In December 2013, we commenced a Phase 1/2 trial for BL-7010 at Tampere Hospital in Finland, a leading site for celiac research. This study was conducted based on an initial medical device submission, under a conditional approval received from the regulatory authorities. In November 2014, we reported the final results of the study. BL-7010 was found to be safe and well tolerated in both single- and repeated-dose administrations. Based on these results, we selected the dosing regimen of one gram, three times per day, of BL-7010 as the optimal repeated dose in the next efficacy study for celiac patients. In January 2016, we received confirmation regarding the classification of BL-7010 as a Class IIb medical device in the European Union.

  Over the last year, we have invested considerable efforts in examining alternative development and commercialization pathways for BL-7010, in addition to the celiac disease pathway, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity. We believe the gluten sensitivity market has a significantly shorter time to market than drug or device pathways, especially in the U.S. market, where the device pathway is not available for BL-7010. We are currently conducting a number of activities towards the development of BL-7010 as a food supplement, including the development of a suitable product formulation, preparation of the documents necessary for a GRAS designation submission, and preparations for a relatively small clinical trial to support the marketing efforts we may conduct regarding gluten and/or gluten sensitivity. We expect to complete these activities by mid-2017 in order to support partnering discussions for the food supplement market in the U.S. and other relevant territories at that time. We will also continue to evaluate the pathway in Europe for celiac disease and will make a decision about the timing and scope of the next efficacy study for European registration later this year.

- BL-5010 is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a Phase 1/2 clinical trial of BL-5010. We have received European confirmation from BSI of the regulatory pathway classification of BL-5010 as a Class IIa medical device. In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma (now a subsidiary of Perrigo Company plc) for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries. During 2015, Omega Pharma conducted a 30-patient, open-label clinical study to evaluate the advantages of BL-5010 in one of the intended OTC indications. Study results indicate that BL-5010 is safe and efficacious. Omega Pharma has received CE Mark approval for BL-5010 and completed the initial manufacturing process automation to support the product launch. The commercial launch of the first OTC indication (warts/verrucas) for this product has commenced and will be gradually carried out by Omega over the next 6-9 months in a number of countries.

Principal Partnering and Collaboration Agreements

In December 2014, we entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. Under the agreement, we intend, in collaboration with Novartis, to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis. Through the date of this report, Novartis has flagged several pre-clinical projects, which we intend to bring into our pipeline over the next few months.

In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for over-the-counter or OTC indications in the territory of Europe, Australia and additional selected countries. We retain all OTC rights to BL-5010 in the United States and the rest of the world, as well as all non-OTC rights on a global basis. Under our out-licensing arrangement with Omega Pharma, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Omega Pharma will sponsor and manufacture BL-5010 in the relevant regions. Omega Pharma will pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. In addition, we will have full access to all clinical and research and development data, as well as manufacturing data, generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights.

In January 2016, we entered into a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. We plan to sponsor and conduct a Phase 2a study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

Other Partnering and Collaboration Agreements

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Bellerophon. Under the agreement, we granted Bellerophon an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injuries to the myocardial tissue of the heart. Under the arrangement, Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or products related thereto. We received an upfront payment of $7.0 million upon the execution of the license agreement. Upon successful completion of the Phase 1/2 clinical trial, Bellerophon paid us a milestone payment of $10.0 million in March 2010, and we are entitled to receive additional milestone and royalty payments upon the occurrence of certain events.

In June 2013, we signed an out-licensing agreement with CTTQ, the leading Chinese pharmaceutical company in the liver disease therapeutic area, granting CTTQ exclusive rights to develop, manufacture and commercialize BL-8030, an orally available treatment for HCV, in China and Hong Kong. In January 2016, we received notice from CTTQ that it was exercising its right to terminate the agreement with us, effective in April 2016. We have also provided notice to the licensors of BL-8030 of the termination of our in-licensing agreement with them, which took effect in early March 2016.

In January 2014, we signed a collaboration agreement with JHL Biotech, or JHL, a biopharmaceutical company that develops, manufactures, and commercializes biologic medicines, pursuant to which we will collaborate with JHL in the development and commercialization of BL-9020, a novel monoclonal antibody in the preclinical development stage for the treatment of Type 1 diabetes. JHL Biotech will be responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and we will be responsible for all pre-clinical development of BL-9020. JHL will have global manufacturing rights to BL-9020, along with development and commercialization rights in China and Southeast Asia, and we will have development and commercialization rights in the rest of the world. In all development and manufacturing of BL-9020, JHL will adhere to FDA guidelines and regulations. Each party will have rights to all development and regulatory data generated under the agreement in order to commercialize BL-9020 in its respective territory. Each party will also be entitled to single-digit royalties on the sale of BL-9020 in the other party's respective territory.

Funding

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding previously received from the Office of the Chief Scientist of the Israeli Ministry of the Economy (OCS), payments received under out-licensing arrangements, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone and royalty payments that we may receive from our existing out-licensing agreements, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of March 31, 2016, we held $45.0 million of cash, cash equivalents and short-term bank deposits.

Recent Company Developments

Pre-Clinical and Clinical Development

BL-8040

In March 2016, we announced positive top-line results from BL-8040's Phase 2a clinical trial in r/r AML. The Phase 2a trial was a multicenter, open-label study under an IND, conducted at ten clinical sites in the U.S. and Israel, and was designed to assess the safety, efficacy pharmacodynamics and pharmacokinetic parameters of BL-8040 in combination with Cytarabine (Ara-C) for the treatment of adult patients with r/r AML. Results of the Phase 2a clinical trial showed that BL-8040, as a single agent and in combination with Cytarabine (Ara-C), was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg, with no major adverse events (n=45). The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving up to two cycles of BL-8040 treatment at doses of 1 mg/kg and higher (n=39). Patients included in the study were patients that had undergone a significant number of prior treatments or that were refractory to induction treatment. Almost all patients received just one cycle of treatment. The data include three compassionate-use patients treated at the study sites under the identical treatment protocol. Historical remission rates in similar patient populations with similar treatment regimens are approximately 20% for Cytarabine on a stand-alone basis. In addition, treatment with BL-8040 continues to show a triple effect on the leukemic cells. First, BL-8040 monotherapy triggered robust mobilization of AML cells from the bone marrow to the peripheral blood, thereby sensitizing these cells to the Ara-C chemotherapy and improving its efficacy. Second, BL-8040 monotherapy showed a direct apoptotic effect on the leukemia cells in the bone marrow. Last, BL-8040 induced leukemia progenitor cells towards differentiation, as evidenced by a decrease in the number of leukemia progenitor cells, along with a three-fold increase in differentiated granulocytes, in the bone marrow biopsy conducted on day 3 of the treatment cycle prior to the Ara-C treatment, as compared to the biopsy performed at baseline. We plan to present detailed results of the study at an upcoming scientific conference.

In March 2016, we also announced the initiation of a Phase 2 trial for BL-8040 as a novel approach for the mobilization and collection of bone marrow stem cells from the peripheral blood circulation. The Phase 2 open-label study is being conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology, and will enroll up to 24 donor/recipient pairs, aged 18-70. The trial is designed to evaluate the ability of BL-8040, as a single agent, to promote stem cell mobilization for allogeneic transplantation. On the donor side, the primary endpoint of the study is the ability of a single injection of BL-8040 to mobilize sufficient amounts of cells for transplantation following up to two leukapheresis collections. On the recipient side, the study aims to evaluate the functionality and engraftment following transplantation of the BL-8040 collected graft. The study will also evaluate the safety and tolerability of BL-8040 in healthy donors, as well as graft durability, the incidence of grade 2-4 acute graft versus host disease (GvHD), and other recipient related parameters in patients who have undergone transplantation of hematopoietic cells mobilized with BL-8040.

Commercialization

BL-5010

In April 2016, we announced that our licensee, Omega Pharma, received CE mark approval for BL-5010. The commercial launch of the first OTC indication for this product has commenced and will be gradually carried out by Omega over the next 6-9 months in a number of countries.

Addition and Termination of Therapeutic Candidates

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. In line with our business strategy, during the period beginning January 1, 2016 through the date of this announcement, we terminated three projects at various stages of development due to lack of efficacy or other scientific considerations: BL-7040, BL-8030 and BL-1110. BL-7040 was intended to treat inflammatory bowel disease; BL-8030, hepatitis C; and BL-1110, neuropathic pain and scleroderma.

Revenues

Our revenues to date have been generated primarily from milestone payments under current and previously existing out-licensing agreements.

We expect our revenues for the next several years to be derived primarily from payments under our current out-licensing agreement with Omega Pharma, our collaboration agreement with Novartis and other potential collaboration arrangements, including future royalties on product sales.

Research and Development

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current major research and development projects:

Project	Status	Expected Near Term Milestone
BL-8040	1. Phase 2a study for AML completed 2. Phase 2b consolidation treatment for AML ongoing 3. Phase 2 study in stem cell mobilization initiated 4. Phase 2a study in pancreatic cancer, in collaboration with Merck, in final planning stages 5. Phase 1/2 study for hMDS and AA initiated 6. Phase 2a study for AML patients with FLT3-ITD mutation in final planning stages	1. Meet with regulatory authorities to discuss next steps in development 2. Completion of enrollment by mid-2017. Top-line results expected in 2018 3. Partial results expected by end of 2016 4. Commencement of study expected in mid-2016 5. Partial results expected by end of 2016 6. Commencement of study expected in H2 2016
BL-7010	Completed Phase 1/2 study; classified as Class IIb medical device in the EU	Submission of package for GRAS designation as food supplement in the U.S.; completion of formulation development as food supplement; initiation of clinical study for marketing purposes as food supplement; determination of appropriate timing for continued medical device development in Europe
BL-5010	Out-licensed to Omega Pharma; CE mark approval obtained; commercial launch of first OTC indication in Europe commenced	Gradual full roll-out of commercial launch over next 6-9 months; selection by Omega of second OTC indication for development; pursuit of potential out-licensing partner(s) for OTC and non-OTC rights still held by us

In addition to the projects set forth above, we have three additional projects in clinical and pre-clinical stages of development (BL-8020, BL-1040 and BL-9020) that are significantly less material to the Company's ongoing research and development expenditures.

Set forth below is a summary of the costs allocated to our main projects on an individual basis, as well as the costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2013, 2014 and 2015; for the three months ended March 31, 2016; and on an aggregate basis since project inception. Certain of such costs were covered by OCS funding, although OCS funds received have not been deducted from the direct project costs in the table.

	Year Ended December 31,			Three Months Ended March 31,	Total Costs Since Project
	2013	2014	2015	2016	Inception
	(in thousands of U.S. dollars)				
BL-8040	3,910	4,698	7,045	1,791	18,167
BL-7010	1,905	3,756	1,657	325	8,477
BL-5010	251	1,282	400	20	4,089
Other projects	5,097	1,537	1,916	399	103,731
Total gross direct project costs	11,163	11,273	11,018	2,535	134,464

From our inception through March 31, 2016, we have incurred research and development expense of approximately $156.7 million. We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain therapeutic candidates or projects in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate.

The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

We expect our research and development expenses to remain our most significant cost as we continue the advancement of our clinical trials and preclinical product development projects and place significant emphasis on in-licensing new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in business development and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, professional fees for outside market research and consulting, legal services related to partnering transactions and travel costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes the pro-rata share of issuance expenses from the placements related to the warrants. In addition, non-operating expense and income includes the initial commitment and finder's fees, as well as other one-time expenses, associated with the initial set-up of a share purchase agreement with Lincoln Park Capital, or LPC.

Financial Expense and Income

Financial expense and income consists of interest earned on our cash, cash equivalents and short-term bank deposits; bank fees and other transactional costs.

Significant Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2015.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Functional and Presentation Currency

From our inception through December 31, 2014, our functional and presentation currency was the New Israeli Shekel, or NIS. Effective January 1, 2015, we changed our functional and reporting currency from the NIS to the U.S. dollar, or dollar, which is the primary currency of the economic environment in which we operate.

Results of Operations – Overview

Revenues

We did not record any revenues during each of the three-month periods ended March 31, 2016 and 2015.

Cost of revenues

We did not record any cost of revenues during each of the three-month periods ended March 31, 2016 and 2015.

Research and development expenses

At December 31, 2013, our drug development pipeline consisted of 10 therapeutic candidates. During 2014, we added a new compound to our pipeline and discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2014 consisted of 10 therapeutic candidates. During 2015, we did not add any new compounds to our pipeline and we discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2015 consisted of nine therapeutic candidates. Subsequent to December 31, 2015, we terminated three therapeutic candidates in our pipeline, so that our drug development pipeline as of the date of this report consists of six therapeutic candidates.

Operating Results Comparison between Periods

Revenues and cost of revenues

See discussion under "Results of Operations - Overview" above.

Research and development expenses

	Three months ended March 31,		
	2015	2016	Increase (decrease)
	(in thousands of U.S. dollars)		
Research and development expenses, net	3,211	2,539	(672)

Research and development expenses for the three months ended March 31, 2016 were $2.5 million, a decrease of $0.7 million, or 20.9%, compared to $3.2 million for the three months ended March 31, 2015. The decrease resulted primarily from the conclusion of one of the clinical trials for BL-8040 in 2015, and the wind-down of a second clinical trial for BL-8040 during the 2016 period.

Sales and marketing expenses

	Three months ended March 31,		
	2015	2016	Increase (decrease)
	(in thousands of U.S. dollars)		
Sales and marketing expenses	260	248	(12)

Sales and marketing expenses for the three months ended March 31, 2016 were $0.2 million, substantially similar to the comparable period in 2015.

General and administrative expenses

	Three months ended March 31,		
	2015	2016	Increase (decrease)
	(in thousands of U.S. dollars)		
General and administrative expenses	856	989	133

General and administrative expenses for the three months ended March 31, 2016 were $1.0 million, an increase of $0.1 million, or 15.5%, compared to $0.9 million for the three months ended March 31, 2015. The small increase was the cumulative effect of an increase in several categories of expenses, none of which individually was material.

Non-operating income (expenses), net

	Three months ended March 31,		
	2015	2016	Increase (decrease)
	(in thousands of U.S. dollars)		
Non-operating income (expenses), net	(40)	148	188

Non-operating income (expenses) for the three months ended March 31, 2016 and 2015 were not material, and primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date).

Financial income (expenses), net

	Three months ended March 31,		
	2015	2016	Increase (decrease)
	(in thousands of U.S. dollars)		
Financial income	73	143	70
Financial expenses	(17)	(4)	13
Net financial income (expenses)	56	139	83

Financial income (expenses), net for the three months ended March 31, 2016 and 2015 were not material, and primarily relate to investment income earned on our bank deposits, as well as banking fees.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, funding from the OCS, and payments received under our strategic licensing arrangements. At March 31, 2016, we held $45.0 million in cash, cash equivalents and short-term bank deposits. We have invested substantially all of our available cash funds in short-term bank deposits.

Pursuant to the share purchase agreement signed with LPC in May 2014, we may sell, from time to time, and at our discretion, up to $20 million of our ADSs to LPC during the 36-month term of the purchase agreement. From the effective date of the purchase agreement through the date of this report, we have sold an aggregate of approximately $4.3 million of our ADSs to LPC, leaving an available balance under the facility of approximately $15.7 million.

Net cash used in operating activities was $4.2 million for the three months ended March 31, 2016, compared with net cash used in operating activities of $3.5 million for the three months ended March 31, 2015. The $0.7 million increase in net cash used in operating activities during the three-month period in 2016, compared to the three-month period in 2015, was primarily the result of a decrease in trade payables and accruals.

Net cash provided by investing activities for the three months ended March 31, 2016 was $1.7 million, compared to net cash used in investing activities of $20.7 million for the three months ended March 31, 2015. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the three months ended March 31, 2016 was $1.6 million, compared to net cash provided by financing activities of $26.5 million for the three months ended March 31, 2015. The decrease in cash flows from financing activities reflects the underwritten public offering which we completed in March 2015.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements into 2018, we will require significant additional financing in the future to fund our operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;

- the magnitude of our general and administrative expenses;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- payments to the OCS.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

Off-Balance Sheet Arrangements

Since inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.